UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE DEFENDANTS' EXPERT TIMOTHY ULATOWSKI**

Mr. Ulatowski is only qualified to address matters of FDA regulation, a topic which is fraught with potential confusion and prejudice. That prejudice is severely magnified by the specific facts of this case. Moreover, Mr. Ulatowski's opinions run contrary to the documented evidence concerning FDA action. Not only is his testimony unreliable, but if admitted it will require an inordinate amount of trial resources and threaten to overwhelm the issues actually under dispute. Finally, Mr. Ulatowski's professional connections to Arizant and the Bair Hugger further heighten the potential for prejudice.

ARGUMENT

I. Mr. Ulatowski's Opinions Regarding FDA Compliance are More Prejudicial than Probative.

Defendants do not point to any authority finding that a defendant's claim of bare compliance with regulations is relevant to a jury's determination of a product defect or

negligence.[1] In fact, copious authority holds the opposite. As the Fourth Circuit stated, "the clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value." *In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair System Products Liability Litigation,* 810 F.3d 913, 920 (4th Cir. 2016). Compliance with the regulatory scheme under 510(k) is not relevant to whether Defendants committed negligent conduct, because "510(k) compliance does not go to the safety of a product." *Hall v. Boston Scientific Corp*., 2015 WL 874888, at *2 (S.D.W.Va. 2015). As the court in *Hall* explained:

> Such conduct is not mitigated by compliance with 510(k), a regulation "intended merely to give manufacturers the freedom to compete." *Lohr,* 518 U.S. at 492. Put differently, the fact that the Obtryx received 510(k) clearance does not make it more or less probable that BSC's conduct in designing the Obtryx warrants punitive damages.

2015 WL 874888, at *2 (S.D.W.Va. 2015) (holding that 510(k) is "not a relevant standard here."); *see also Lewis v. Johnson & Johnson*, 991 F.Supp.2d 748, 755 (S.D.W.Va. 2014) ("Because the FDA's 510(k) clearance of the [product] does not speak to its safety or efficacy, it is irrelevant to this case and inadmissible under Rule 402.").

Defendants cite materials which they claim stand for the proposition that "the 510(k) process does, in fact, evaluate safety and effectiveness."[2] However, these statements directly conflict with other findings from the agency. The internal audit

[1] In support of its argument, Defendants cite cases from this district in which regulatory matters were admitted, but in these cases, the evidence concerned allegations of specific regulatory violations, not allegations of compliance. *See Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 990 (D. Minn. 2013); *Lillebo v. Zimmer, Inc.*, No. 03-2919, 2005 WL 388598, at *4-5 (D. Minn. Feb. 16, 2005).

[2] Def. Opp. at 11.

ordered by the FDA Commissioner in 2011 found "that the 510(k) process was not designed to determine whether a new device provides a reasonable assurance of safety."[3] These statements also conflict with the findings of the great weight of judicial authority. *See, e.g, In re C.R. Bard, Inc*., 810 F.3d at 920 (The regulation "operate[s] to exempt devices from rigorous safety review procedures."). Ultimately, unraveling these conflicting statements will require a mini-trial not only on the nature and rigor of 510(k) clearances, but also an exhaustive dispute over the way that regulatory process was applied to this specific device.

II. Mr. Ulatowski's Methodology is Unreliable.

A. Mr. Ulatowski's Opinion on FDA Clearance is Unreliable.

In forming opinions about the FDA decision-making process on the Bair Hugger, Mr. Ulatowski's methodology must show respect for the documentary evidence. Yet Defendants cannot ignore that the records of that decision-making process contradict his assertions. This dispute concerns "the determinations made by the reviewer on the path to ultimately concluding that the Bair Hugger models, which for the first time were being cleared for use in the operating room, were 'substantially equivalent' to predicate devices."[4]

These documents were not on Mr. Ulatowski's reliance list in this case. Moreover, during his deposition, Mr. Ulatowski freely agreed that his opinions were made on the

[3] *See* Ulatowski Dep. at 65:17-19.
[4] Def. Opp. at 15.

assumption that 510(k) decision-making documents were unavailable. In fact, it was Mr. Ulatowski who volunteered this assumption:

> Q. What did the FDA do to determine that the Bair Hugger's expansion of use into the OR did not pose any new questions of safety?
>
> A. Well we don't have available to us the reviews by FDA, so we don't -- we cannot benefit from that.[5]

Thus, even if Mr. Ulatowski was provided the document in the *Walton* matter, it did not factor into his opinions. Ultimately, it is immaterial whether he reviewed the document, because the FDA review was conducted in a manner totally at odds with Mr. Ulatowski's opinions. Mr. Ulatowski believed that a change in indications for use had been reviewed for potential safety impact, yet the documents show that due to a reviewer error, the change in clinical use was not recognized or evaluated.

Defendants cite other testimony in which Mr. Ulatowski equivocates that perhaps a change to use during surgeries is not actually a change in indications for use.[6] Mr. Ultatowski has no support for this position. A fundamental change in intended clinical use undoubtedly changes the product's indications for use. To hold otherwise is such a radical, counter-intuitive position that it would require some substantive support. But Mr. Ulatowski has none. Instead, he could only claim the change in clinical use was something "he viewed as possibly insignificant in the FDA's eyes." (Def. Br. 17, citing Ultatowski at 145:21-147:3). But even the authority cited by Defendants agree that Mr. Ultowski cannot speculate on what the FDA's findings would be. *See, e.g., Braun, et al.*

[5] *See* Ulatowski Dep. at 87:23 to 88:3.
[6] Def. Opp. at 16.

v. Medtronic Sofamor Danek, No. 2:10-cv-01283-RJS, ECF No. 535 (D.Utah Feb. 5., 2014) (precluding Mr. Ulatowski from "speculat[ing] on what FDA would have done").[7] Mr. Ulatowski can only rely on the evidence, and that evidence does not support an opinion that the Bair Hugger was reviewed for safety in the operating room.

Nonetheless, Defendants cite Mr. Ulatowski's conjecture that there "would have been an assessment to one degree or another of the differences, including differences and their impact on safety and effectiveness." (Def. Opp. 17, citing Ultaowski Dep. at 163:13-16). However, Mr. Ulatowski has no documentation to support this speculation about "what the FDA would have done," *see Braun*, *supra*, and the existing documentation contradicts Mr. Ulatowski, showing no inquiry was made as to new effects on safety:[8]

[redacted]

As such, his opinions regarding the evaluation of the Bair Hugger for safety issues in the operating room are unreliable and must be excluded.

B. Mr. Ulatowski's Opinion on the Need for Warnings is Unreliable.

Mr. Ulatowski concluded that Defendants acted reasonably in not providing a warning because a causal relationship had not been proven. However, FDA guidance documents caution that this factor should be irrelevant in a manufacturer's decision.

[7] Attached to Defendants' Opp. as Exhibit 10.
[8] *See* Pltf's Motion, Exhibit 3 (510(k) Decision-Making Documentation, 3MBH00047439 – 42).

Defendants respond by noting that "the lack of a causal relationship was *one of several factors*" noted by Mr. Ulatowski.[9] However, Mr. Ultatowski cannot cite a single reason that a company should consider this factor *at all* when determining whether to issue a warning.

Defendants claim that "Plaintiffs simply disagree with Mr. Ulatowski's reasoning rather than the method underlying it," but it is Mr. Ulatowski's method which is at the heart of this dispute. In determining whether Defendants met their obligations under FDA regulations – the sole subject matter of his proposed testimony – Mr. Ulatowski's methodology must show faith to FDA guidance materials.

Ultimately, it is misleading and confusing to allow Mr. Ulatowski to tell the jury that one of the reasons Defendants need not give a warning is because of a lack of a proven causal relationship when FDA documents state the opposite. Moreover, the entire debate further underscores the excessive time and effort the parties would be forced to expend to unravel FDA issues. Mr. Ulatowski's presumed authority in the eyes of the jury and his personal connections to the Bair Hugger poses further confusion and prejudice on these issues.

C. Mr. Ulatowski's Opinion about the Assurance of Safety of Class II Devices is Unreliable.

Finally, Plaintiffs noted that Mr. Ulatowski has no reliable basis to support his opinion that "there is reasonable assurance that a Class II device is safe and effective

[9] Def. Opp. at 19.

when it meets all general controls and any special controls."[10] Defendants counter that "Mr. Ulatowski's statement is a quote directly from 21 U.S.C. § 360(c)."[11] But Mr. Ulatowski is not testifying to instruct the jury on the law, for that is the role of the Court. Moreover, as explained by the Fourth Circuit, these statements in the FDA regulations provide little assurance:

> Bald assertions by the FDA do little to alter the analysis of the basic question: How much information does 510(k) clearance provide a jury about the safety of the underlying product, and is the value of this information substantially outweighed by the possibility of prejudice in a particular case?

In re C.R. Bard, Inc., 810 F.3d at 921. Like in *Bard*, the risk is high, even more so given the factual peculiarities of this case. If Mr. Ulatowski seeks to tell the jury that the regulatory scheme covering the Bair Hugger ensured its safety, he must offer scientific or technical evidence, not a recitation of a statute. Likewise, Mr. Ulatowski's bare experience at the FDA cannot reliably support the opinion that all regulatory-compliant Class II devices are reasonably ensured to be safe.

III. Mr. Ulatowski's Personal Involvement Cannot be Excised from the Case, and it Poses Real Prejudice.

It is difficult to ignore the potential prejudice caused by Mr. Ulatowski's prior associations with the Bair Hugger. Mr. Ulatowski's prior favorable actions towards Arizant and the Bair Hugger pose the risk, at least subconsciously, of causing Mr. Ulatowski to treat the device more charitably when coming to his conclusions. But at

[10] Def. Opp. at 20.
[11] *Id.*

heart, Defendants misunderstand the fundamentals of Plaintiffs' argument. Plaintiffs do not allege that Mr. Ulatowski's contacts represent an irreconcilable ethical conflict, but instead that his connection to the Bair Hugger risks the introduction of significant prejudice and jury confusion.

Defendants claim there will be no risk of prejudice, because they do not "intend to suggest to the jury that Mr. Ulatowski speaks for the FDA."[12] Yet Defendants have no need to make such a suggestion, as Mr. Ulatowski's presence alone risks accomplishing that prejudicial task. Moreover, Defendants claim they will not offer evidence relating to Mr. Ulatowski's professional contacts with the Bair Hugger, but Plaintiffs will likely be offering the documents relating to those events, as they are relevant to other issues. In the totality of facts presented, this case presents an unusually high potential for confusion and prejudice on all issues relating to the FDA, and Mr. Ulatowski's personal involvement in those issues worsens that risk.

IV. Mr. Ulatowski is not Qualified to Address Non-Regulatory Matters.

Defendants response appears to concede Plaintiffs' point with respect to Mr. Ulatowski giving opinions outside his area of expertise, at least with respect to medical causation. However, much like Mr. Ulatowski himself, Defendants remain cryptic about whether Mr. Ultatowski intends to testify about non-regulatory matters or whether he "is competent to opine on those matters."[13] Yet there should be no ambiguity that Mr. Ulatowski has no expertise in orthopedic surgery, biomedical engineering, filtration,

[12] Def. Opp. at 22.
[13] Def. Opp. at 23.

HVAC, operating room design, particulate flow, statistical analysis, infectious disease, or epidemiology.[14] An unequivocal order from the Court is necessary because while Mr. Ulatowski testified that his report does not contain these kind of opinions, in terms of trial he stated: "But who knows?"[15]

CONCLUSION

Mr. Ulatowski's only qualifications concern FDA regulations. These regulatory matters invite confusion and prejudice, especially under the specific facts of this case. Moreover, Mr. Ulatowski's opinions run contrary to the documented evidence concerning FDA decision-making. Not only is his testimony unreliable, but if admitted it will require a mini-trial on a host of issues with no actual relevance to matters before the jury. Finally, Mr. Ulatowski's professional connections to Arizant and the Bair Hugger further heighten the potential for prejudice.

Respectfully submitted,

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[14] *See* Ulatowski Dep. at 31:2-5; 34:12-14; 271:1-23; 364:4-10.
[15] *Id.* at 271:25.

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